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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/697,283 | 10/31/2003 | James Kleinmeyer | ARL 00-17 D1 | 8443 |

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U S ARMY RESEARCH LABORATORY
ATTN AMSRL CS CC IP
2800 POWDER MILL RD
ADELPHI, MD 207831197

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| EXAMINER |
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DEL SOLE, JOSEPH S

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| ART UNIT | PAPER NUMBER |
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1722

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/697,283

Applicant(s)

KLEINMEYER ET AL.

Examiner

Joseph S. Del Sole

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 10, 11 and 13-21 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-9, drawn to an electro-spinning process, classified in class 264, subclass 452.
 - II. Claims 10-21, drawn to an electro-spinning apparatus, classified in class 425, subclass 174.8E.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another and materially different apparatus such as an apparatus which also includes a heated extruder for liquefying the polymer, or an apparatus which also includes a roller for drawing the filament through the electrostatic field.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Edward L. Stolarun (by Examiner Tentoni, AU1732) on 02 August 2005 a provisional election was made with traverse to prosecute the invention of Group II, claims 10-21. Affirmation of this election must be made by

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applicant in replying to this Office action. Claims 1-9 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/757,272, filed 1/10/01. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted

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during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge

under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Information Disclosure Statement

7. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

8. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because a) the lines, numbers and letters are not uniform, clean and well defined (of a generally poor quality) in Figure 1 from 10/31/2003 (37 CFR 1.84(l)). Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Double Patenting

9. Applicant is advised that should claim 11 be found allowable, claim 14 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two

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claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 11 and 14 both recite a plurality of electrodes, the added limitation in claim 14 "biased to provide a linear field gradient between the die and the filament collection means" is a limitation to the intended use of the electrode means and does not further limit the claim. Since claim 14 is not further limited by this limitation it is identical to claim 11 in scope.

Claim Objections

10. Claim 17 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The positive or negative nature of the biases is a process limitation since any device that can be operated at a bias can have the bias easily switch depending on the intended use of the apparatus.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 10, 15, 16, 17, 18 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Formhals (2,323,025).

Formhals teaches an electrospinning apparatus having an electrically conductive extrusion die (Fig 1; #2); an electrically conductive filament collection means spaced from the die orifice (Fig 1, #19, the Examiner notes that the collection means need not be charged and may be grounded as stated at claim 18); an electrode means (Fig 1, #16) positioned between the die orifice and the filament collection means, the electrode means having n chargeable electrodes, wherein n is an integer of from 1 to 50; means for providing a first electrical bias to the die (Fig 1, #11) and an $(n+2)^{\text{th}}$ electrical bias to filament collection means (Fig 1, the collection means is grounded); means for providing a second electrical bias to the electrode means (Fig 1, #15); the collection means is spaced at least about 3 centimeters from the die orifice; and the chargeable electrodes are independently biased.

The Examiner notes that the claims requirement of "said second electrical bias having the same polarity and a magnitude equal to or less than that of the first electrical bias" is not a structural limitation but rather a limitation directed to the manner in which the apparatus is operated. It is enough if the apparatus is capable of being operated in the manner set forth and the apparatus of this invention is capable of such.

13. Claims 10, 11, 14, 15, 16, 17, 18 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Hollberg et al (3,689,608).

Hollberg et al teach an electrospinning apparatus having an electrically conductive extrusion die (Fig 2, due to #s 22' and 25'); an electrically conductive filament collection means spaced from the die orifice (Fig 1, #9); an electrode means (Fig 1, #s 22 and 20) positioned between the die orifice and the filament collection

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means, the electrode means having n chargeable electrodes, wherein n is an integer of from 1 to 50; means for providing a first electrical bias to the die (Fig 2, #s 22', 21 and 25) and an $(n+2)^{\text{th}}$ electrical bias to filament collection means (Fig 1, #37); means for providing a second electrical bias to the electrode means (Fig 1, #s 24 and 21); there are a plurality of electrode means (Fig 1, #s 20 and 22); the collection means is spaced at least about 3 centimeters from the die orifice; and the chargeable electrodes are independently biased.

The Examiner notes that the claims requirement of "said second electrical bias having the same polarity and a magnitude equal to or less than that of the first electrical bias" is not a structural limitation but rather a limitation directed to the manner in which the apparatus is operated. It is enough if the apparatus is capable of being operated in the manner set forth and the apparatus of this invention is capable of such.

14. Claims 10, 15, 16, 17, 18 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Childs (2,338,570).

Childs teaches an electrospinning apparatus having an electrically conductive extrusion die (Fig 1, #4); an electrically conductive filament collection means spaced from the die orifice (Fig 1, #s 19 and 26, the Examiner notes that the collection means need not be charged and may be grounded as stated at claim 18); an electrode means (Fig 1, #17) positioned between the die orifice and the filament collection means, the electrode means having n chargeable electrodes, wherein n is an integer of from 1 to 50; means for providing a first electrical bias to the die (Fig 1, #15) and an $(n+2)^{\text{th}}$ electrical bias to filament collection means (Fig 1, the collection means is grounded);

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means for providing a second electrical bias to the electrode means (Fig 1, #16); the collection means is spaced at least about 3 centimeters from the die orifice; and the chargeable electrodes are independently biased.

The Examiner notes that the claims requirement of "said second electrical bias having the same polarity and a magnitude equal to or less than that of the first electrical bias" is not a structural limitation but rather a limitation directed to the manner in which the apparatus is operated. It is enough if the apparatus is capable of being operated in the manner set forth and the apparatus of this invention is capable of such.

15. Claims 10, 15, 16, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Soane (5,064,577).

Soane teaches an electrospinning apparatus having an electrically conductive extrusion die (Fig 1, #14); an electrically conductive filament collection means spaced from the die orifice (Fig 1, #27, the Examiner notes that the collection means need not be charged and may be grounded as stated at claim 18); an electrode means (Fig 1, #16) positioned between the die orifice and the filament collection means, the electrode means having n chargeable electrodes, wherein n is an integer of from 1 to 50; means for providing a first electrical bias to the die (Fig 1, #12) and an $(n+2)^{\text{th}}$ electrical bias to filament collection means (Fig 1, the collection means is grounded); means for providing a second electrical bias to the electrode means (Fig 1, #12); the collection means is spaced at least about 3 centimeters from the die orifice.

The Examiner notes that the claims requirement of "said second electrical bias having the same polarity and a magnitude equal to or less than that of the first electrical

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bias" is not a structural limitation but rather a limitation directed to the manner in which the apparatus is operated. It is enough if the apparatus is capable of being operated in the manner set forth and the apparatus of this invention is capable of such.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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19. Claims 13 and 19-20 rejected under 35 U.S.C. 103(a) as being unpatentable over Hollberg et al (3,689,608).

Hollberg et al teach the apparatus as discussed above.

While Hollberg et al teach more than 1 electrode, Hollberg et al fail to teach more than two electrodes.

Regarding the duplication of parts as described in claims 13, 19 and 20, such duplication of parts has no patentable significance unless new and unexpected results are produced. In re Harza, 124 USPQ 378 (CCPA 1960).

Allowable Subject Matter

20. Claim 12 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

21. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fails to teach or suggest the electrodes as claimed in the independent claim being plural in number and being longitudinally spaced.

Correspondence

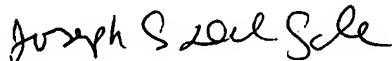
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph S. Del Sole whose telephone number is (571) 272-1130. The examiner can normally be reached on Monday through Friday from 8:30 A.M. to 5:00 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, Mr. Duane Smith can be reached at (571) 272-1166. The official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for both non-after finals and for after finals.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from the either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 886-217-9197 (toll-free).

A handwritten signature in cursive script, reading "Joseph S. Del Sole".

Joseph S. Del Sole
September 26, 2005